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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/830,981

10/29/2001

Eberhard Hildt

033392-001

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09/13/2005

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EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/830,981

Applicant(s)

HILDT ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 30-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This action is in response to paper filed 10 June 2005.

Claims 30-41 are under consideration in this action.

### ***Rejections Withdrawn***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21-29 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been canceled.

Claims 21-29 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims have been canceled.

### ***Claim Rejections - 35 USC § 102***

Claims 21-23, and 27 were rejected under 35 U.S.C. 102(b) as being anticipated by Van Nieuwstadt *et al.* (WO 98/50426).

The claims have been canceled.

Claim 21 was rejected under 35 U.S.C. 102(b) as being anticipated by Evotec Biosystems (DE 19808258).

Claim 21 is drawn to a 12 mer peptide with residues as defined in the claim.

The claim has been canceled.

### ***Rejections Necessitated By Amendment***

#### ***Claim Rejections - 35 USC § 112***

Claims 30-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for all peptides that are contained in the genus of peptides of claim 30 or fusion proteins that comprise the motif. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate with these claims.

Applicant argues that the examiner is clearly wrong, that the fusion of a polypeptide to the CPP will enhance the transport into cells, and that one of skill in the art would be able to practice the invention of claims 31-38.

Applicant's arguments have been fully considered and not found persuasive.

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The claims are drawn to a product not a method of transport into a cell. Claim 30 is drawn to a genus of peptides (smaller than encompassed by claim 21) and applicant has only shown one to function as a fusion protein. Other members of the genus have not been shown to work. Other fusions have not been shown to work as outlined in the rejection.

Claims 31-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant disclosure, the applicants have only disclosed the sequence identified as SEQ ID NO: 4 (DHBV) which is directed to the cell permeability peptide (CPP) linked to a second polypeptide (Example 4). No other sequences which "comprise, comprises, or comprising" SEQ ID NO: 4 were disclosed. The specification does not set forth the metes and bounds that encompass the motif of claim 21, there is not enough information about it in literature either to guide the one of skill in the art to predict the undisclosed peptides will function as claimed. Therefore, the claims do not meet the written description provision of 35 USC 112, first paragraph.

Applicant argues that the term fusion protein is well known in the art and that the fusions are disclosed.

Applicant's arguments have been fully considered and not found persuasive.

Applicant has only shown one CPP to function (the genus claimed now is smaller) and has not shown that the fused proteins will still function.

***Claim Rejections - 35 USC § 102***

Claims 31, 32, and 36 are rejected under 35 U.S.C. 102(b) as anticipated by Hildt *et al.* (1995 Oncogene, from IDS).

The claims are drawn to a fusion protein comprising a virus coat fragment and a cell permeability peptide that is defined by the sequence ID#s recited in claim 30. The claims are treated as product by process and require only a polypeptide that comprises the sequence of the motif or SEQ ID# because once the polypeptide is made, it reads on any peptide that contains the sequence.

Applicant argues that fusion is well known in the art and defined on pages 4-5 of the specification. Applicant also argues that claims 32 and 36 require covalently linkage to oligopeptide and thus are not natural HBV proteins.

Applicant's arguments have been fully considered and not found persuasive.

It is not apparent to the examiner where the specification limits the meaning to non-natural HBV proteins. The definition on page 4 includes viral proteins and does not require heterologous peptide fusion as applicant argues. Claims 32 and 36 are fusion proteins and are not changed by the limitation in claim 31.

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Claims 31-32, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by NCBI Accession # 540642 (protein).

Applicant argues that the sequence does not anticipate claim 30 and that it does not anticipate the fusion protein claims.

Applicant's arguments have been fully considered and found persuasive in part.

Claim 30 is no longer rejection.

As discussed above, the limitation of fusion protein does not exclude the natural HBV clones.

Claims 31-32, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by NCBI Accession # 138800 (protein).

Applicant argues that the sequence does not anticipate claim 30 and that it does not anticipate the fusion protein claims.

Applicant's arguments have been fully considered and found persuasive in part.

Claim 30 is no longer rejection.

As discussed above, the limitation of fusion protein does not exclude the natural HBV clones.

### ***Claim Rejections - 35 USC § 103***

Claims 30 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hildt *et al.* (1995 Oncogene, from IDS).

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Applicant argues that while the reference is discussed in the article, one would not have been to isolate the 12-mer peptide.

Applicant's arguments have been fully considered and not found persuasive.

The region is clearly indicated and if it had been made as an isolated peptide, the rejection would have been based on 35 USC 102. The 12-mer is clearly pointed to and thus a 12-mer peptide is obvious.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.




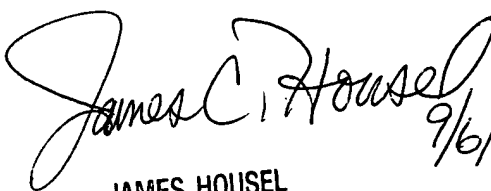
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Myron G. Hill  
Patent Examiner  
26 August 2005

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
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9/6/05